



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Note to Reader
September 9, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

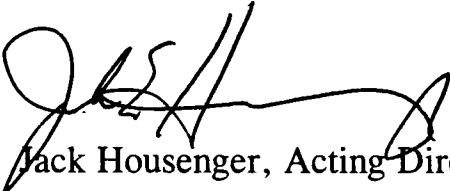
There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.



Jack Housenger, Acting Director
Special Review and Reregistration
Division

March 27, 1998

MEMORANDUM

SUBJECT: Review of an Acute Probabilistic Assessment “Dietary Exposure and Risk Assessment for Terbufos Residues in/on Bananas, Coffee, Field Corn, Sweet Corn, Sugar Beets, Sorghum, and Drinking Water” in Support of the Reregistration of Terbufos (PC Code 105001, MRID 444070-01)

FROM: Elizabeth A. Doyle, Chief
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The subject study was reviewed for conformity with the OPP guidance on the conduct of acute dietary risk assessments and for relevance to the reregistration of terbufos. The study used the Continuing Survey for Food Intakes by Individuals (1989-1991) database, a consumption database acceptable to OPP. Percent crop treated data and residue data were applied in accordance with OPP guidance. The toxicological endpoint used in the assessment was an NOEL of 0.005 mg/kg BW/day in a one month oral dog study. The effect at the next dose (0.015 mg/kg BW/day) was plasma cholinesterase inhibition.

This report presented a dietary risk assessment with and without water included. The inclusion of water in a probabilistic assessment is not an acceptable practice at this time. Therefore, only the MOEs for the assessment without water were included for consideration in this report.

The assessment also included green coffee, a use that was not approved and therefore is not required to be included in a dietary risk assessment. The contribution from coffee to the risk assessment can not be directly subtracted from the probabilistic assessment. Therefore, it is impossible to tell what the contribution from coffee is to the final risk estimates. It should be noted, however, that the relative contribution from coffee in the chronic analysis was small compared to other commodities.

The results of the assessment are presented in the table below. At the time of this review, an MOE of 300 is required. An extra 3x safety factor was recommended for special sensitivity to

infants and children. The values in the table below reflect MOEs at the 99.9th percentile of exposure. In the assessment provided, no breakout for non-nursing infants was provided. The assessment for all infants includes the non-nursing subgroup, however, nursing and non-nursing infants have markedly different food consumption patterns. All subgroups had MOEs less than 300, and only the subgroup Women (13 years and older) had MOEs in excess of 100.

MOEs for Acute Dietary Risk from Terbufos*		
Population Subgroup	Exposure (mg/kg BW/day)	Margin of Exposure
Total US Population	0.000060	83
Children (1-6 years)	0.000115	43
Children (7-12 years)	0.000061	82
All Infants	0.000094	53
Women (13 years and older)	0.000033	151

*Reflects exposure at the 99.9th percentile of exposure.